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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/757,720

01/15/2004

Harm M. Deckers

9369-289

3856

1059 7590 08/14/2008

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EXAMINER

HORNING, MICHELLE S

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

08/14/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/757,720	<b>Applicant(s)</b> DECKERS ET AL.	
	<b>Examiner</b> MICHELLE HORNING	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This office action is responsive to communication filed 5/14/2008. The status of the claims is as follows: claims 1-7 are under current examination.

The following have been withdrawn due to amendments:

1. Objection to the Specification; and
2. 35 USC 112, 2<sup>nd</sup> paragraph.

### ***Claim Rejections - 35 USC § 102-MAINTAINED***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Parmenter et al (1995).**

**Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Moloney.**

### ***Response to Arguments***

Applicant's arguments filed 5/14/2008 have been fully considered but they are not persuasive. Applicant provides the following arguments regarding both rejections above: 1. both references do not teach step (d), 2. both references do not teach step (e) and 3. Parmenter et al does not teach an antigen. The arguments are discussed individually below.

Step (d) comprises washing the oil bodies to obtain washed oil body preparation comprising the antigen. As noted in the previous action (page 5), the instant specification defines the term “washing the oil bodies” as any process that removes cellular contaminants or undesirable properties and such methods may include separation methods such as centrifugation. Parmenter et al provides a step of centrifugation in order to remove insoluble fractions (see Isolation and extraction of seed proteins, page 1170 of this reference). With respect to the teachings of Moloney, this reference provides the following recitation (Paragraph 5, Detailed Description):

The use of an oil body protein as a carrier or targeting means provides a simple mechanism to recover proteins. The chimeric protein associated with the oil body or reconstituted oil body fraction is separated away from the bulk of cellular components in a single step (such as centrifugation size exclusion or floatation); the protein is also protected from degradation during extraction as the separation also reduces contact of the proteins with non-specific proteases. Thus, both references meet the limitation of step (d).

Step (e) comprises “formulating the washed oil bodies associated with the antigen into an immunogenic formulation”. Note that obtaining an immunogenic formulation is not an active step and while both references achieve washed oil bodies associated with the antigen following the claimed steps, this would lead to the same result. An “immunogenic” characteristic is considered an inherent property and all

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foreign materials introduced into a body would induce an immune response. In the claimed methods, the formulation is not in contact with any immune system and thus, an "immunogenic" formulation is further characterized as an intended use for the formulation. Regarding the term "antigen" in step (e), Parmenter et al provides the incorporation of a recombinantly produced protein into the oil body, and this protein meets the broad definition for "antigen" provided by the Applicant. This is discussed further below.

Applicant contends that Parmenter et al does not teach using an antigen. As clearly discussed in the previous action (page 5), the instant specification defines an antigen as "any molecule to which one wishes to elicit an immune response" (see specification, paragraph 160). Further, paragraph 129 provides the following teaching: "The scope of the invention is not limited by the type of antigen used or the means by which the antigen is produced. Antigens may consist of peptides, proteins, carbohydrate or synthetically produced chemicals. The antigen may be similar or identical to the natural molecule against which an immune response is desired or may simply resemble the natural molecule sufficiently to be able to induce a response against the natural molecule. Due to the wide range of possibilities for production and use of antigens it is impossible to provide a comprehensive list of potential antigens that could be included in immunizations with oil bodies and thus only examples that may be reflective of the type of antigens that could be considered are provided." Thus, an antigen can be *anything*; Parmenter et al successfully provides a recombinantly produced protein into the oil body, meeting the definition for "antigen" as defined by the specification.

***Conclusion***

NO CLAIM IS ALLOWED. No argument is found persuasive.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MICHELLE HORNING** whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/  
Examiner, Art Unit 1648

/Zachariah Lucas/  
Primary Examiner, Art Unit 1648